AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions and listings of claims in the application:

LISTING OF CLAIMS:

1-48 (Cancelled).

49. (Amended) An expandable medical device comprising:

a substantially cylindrical expandable medical device body formed of a plurality of struts;

a plurality of openings in the plurality of struts; ~~and~~

a plurality of beneficial agent layers formed in the openings, wherein the plurality of beneficial agent layers include a first active agent arranged for delivery according to a first release profile and a second active agent arranged for delivery according to a second release profile, wherein the first and second release profiles are different; and

a barrier layer adjacent a luminal side of the device body which blocks or retards delivery of the first and second active agents to the luminal side of the device body through the openings.

50. (Previously Presented) The device of Claim 49, wherein the first and second active agents are arranged to be delivered to a mural side of the device body.

51. (Previously Presented) The device of Claim 50, wherein the first active agent is an anti-proliferative and the second active agent is an anti-inflammatory.

52. (Cancelled).

53. (Amended) The device of Claim ~~52~~ 50, wherein the barrier layer is

formed within the openings.

54-55. (Cancelled).

56. (Previously Presented) The device of Claim 49, wherein the first and second release profiles are designed to coordinate with cellular biochemical processes.

57. (Previously Presented) The device of Claim 49, wherein the first and second release profiles are of different duration.

58. (Previously Presented) The device of Claim 49, wherein the first release profile includes programmable bursts.

59. (Amended) An expandable medical device comprising:

a substantially cylindrical expandable medical device body formed of a plurality of struts;

a plurality of openings in the plurality of struts; and

a plurality of beneficial agent layers formed in the openings, wherein the plurality of beneficial agent layers include a first active agent layer arranged for delivery primarily to a first side of the device body and a second active agent layer arranged for delivery to ~~a~~ the first side of the device body.

60. (Previously Presented) The device of Claim 59, wherein the first and second active agent layers include different active agents.

61. (Previously Presented) The device of Claim 59, wherein the first and second active agent layers include the same active agent.

62. (Previously Presented) The device of Claim 59, wherein the first and second active agent layers include the same active agent in different concentrations.

63.-66. (Cancelled).

67. (Previously Presented) A method of forming an expandable medical device comprising:

(a) forming a substantially cylindrical expandable medical device body formed of a plurality of struts with a plurality of openings in the plurality of struts;

(b) forming a solution of a beneficial agent, polymer carrier, and a solvent;

(c) delivering the solution into the opening;

(d) evaporating the solvent to form a solid layer of beneficial agent and carrier; and

(e) repeating steps (c) and (d).

68. (Previously Presented) The method of Claim 67, further comprising forming a second solution of a second beneficial agent, polymer carrier, and solvent and delivering the second solution into the opening on top of the layers of beneficial agent.

69. (Previously Presented) The method of Claim 67, wherein the beneficial agent is an active drug.

70. (Previously Presented) The method of Claim 67, wherein the beneficial agent is an anti-proliferative.

71. (Previously Presented) The method of Claim 67, wherein the beneficial agent is an anti-inflammatory.

72. (Previously Presented) The method of Claim 67, wherein the beneficial agent is an antirestenotic.

73. (Previously Presented) The method of Claim 67, wherein the beneficial agent is a protein drug.

74. (Amended) An expandable medical device comprising:

a substantially cylindrical expandable medical device body formed of a plurality of struts;

a plurality of openings in the plurality of struts; ~~and~~

a first active agent contained in the plurality of openings and arranged for delivery according to a first release profile; ~~and~~

a second active agent contained in the plurality of openings and arranged for delivery according to a second release profile, wherein the first and second release profiles are different; and

wherein the first and second active agents are arranged to be delivered to a first side of the device body.

75. (Previously Presented) The device of Claim 74, wherein the first and second active agents are arranged to be delivered to a mural side of the device body.

76. (Previously Presented) The device of Claim 75, wherein the first active agent is an anti-proliferative and the second active agent is an anti-inflammatory.

77. (Previously Presented) The device of Claim 75, further comprising a barrier layer adjacent a luminal side of the device body which blocks or retards delivery of the first and second active agents to the luminal side of the device body through the openings.

78. (Previously Presented) The device of Claim 77, wherein the barrier layer is formed within the openings.

79.-80. (Cancelled).

81. (Previously Presented) The device of Claim 74, wherein the first and second release profiles are designed to coordinate with cellular biochemical processes.

82. (Previously Presented) The device of Claim 74, wherein the first and second release profiles are of different duration.

83. (Previously Presented) The device of Claim 74, wherein the first release profile includes programmable bursts.

84. (New) The device of Claim 49, wherein the plurality of openings are laser drilled through holes and the device body is a one piece cylindrical structure.

85. (New) The device of Claim 59, wherein the plurality of openings are laser drilled through holes and the device body is a one piece cylindrical structure.

86. (New) The device of Claim 74, wherein the plurality of openings are laser drilled through holes and the device body is a one piece cylindrical structure.

Restriction Requirement

Applicant hereby confirms the election of Group I (claims 49-66 and 74-83) and Species A (claims 49-53, 56-66, 74-78, and 81-83). In the Office Action, claim 62 has been improperly indicated as being drawn to a non-elected species, and has been withdrawn and has been withdrawn by the Examiner. Applicant respectfully requests consideration of claim 62.

Formalities

In the Office Action, claims 59 and 65 have been objected to because of formalities which have been corrected in the foregoing amendments.

Rejections under 35 U.S.C. 102 -- Burkoth et al.

Claims 49-53, 56, 57, 59-61, 63-66, 74-78, 81, and 82 have been rejected under 35 U.S.C. 102(b) as being anticipated by Burkoth et al.

Burkoth et al. describes a directional drug delivery stent. In FIG. 5 of Burkoth et al. a single agent 23 is delivered through a membrane 34 to a vessel wall 24. In FIGS. 9 and 10 of Burkoth et al., two agents 23 and 25 are delivered in opposite directions form the stent. However, there is no teaching or suggestion in Burkoth et al. to use a barrier layer to deliver two active agents from a stent in the same direction (i.e., both luminally or both morally). In fact, the only delivery of multiple active agents described in Burkoth et al. is the situation of FIGS. 9 and 10 where the agents are delivered in opposite directions.

Claim 49 has been amended to incorporate the barrier layer from dependent claim 52. Amended claim 49 recites an expandable medical device having a plurality of openings and first and second active agents within the openings. Claim 49 also recites a barrier layer adjacent a luminal side of the device body which block or retards delivery of the first and second active agents to the luminal side of the device body through the openings. This claimed configuration allows the delivery of two agents to the vessel wall with different release profiles.

Burkoth et al. does not teach or suggest a barrier layer adjacent a luminal side of the device body. Further Burkoth et al. does not disclose two active agents for delivery to the same side of the device body. Accordingly, Claim 49 cannot be anticipated by Burkoth et al.

Claim 59 recites an expandable medical device with a plurality of openings and first and second active agent layers. The first and second active agent layers are arranged for delivery to a first side of the device body. As discussed above, Burkoth et al. does not teach or suggest delivery of two active agents from a same side of a device body.

Claim 74 recites an expandable medical device including a plurality of openings containing first and second active agents, wherein the first and second active agents are arranged to be delivered to a first side of the device body. As described previously, Burkoth et al. does not teach or suggest delivery of first and second active agents to the same side of the stent (i.e. both luminally or both murally).

Rejections under 35 U.S.C. 102 – Santini, Jr. et al.

Claims 49-53, 56-61, 63-66, 74-78, and 81-82 have been rejected under 35 U.S.C. 102(b) as being anticipated by Santini, Jr. et al.

Santini, Jr. et al. describes microchip devices which can be attached to the inside of a stent for drug delivery. (see column 15, lines 1-29) The microchip devices of Santini include a device of FIG. 2d which has two substrates 510a and 510b, two reservoirs 520a and 520b, and two agents 540a and 540b. The two agent drug delivery device of Santini (FIG. 2d) is formed by placing two drug delivery devices on top of one another.

Santini also states that the drug reservoirs can be formed as part of the stent itself. However, there is no teaching or suggestion in Santini of forming a stent with two drug reservoirs for two agents. A stent configuration with two drugs of Santini cannot be formed into the struts of a stent because the substrate stacking methods of forming the chips described in Santini are not useable on a stent. Therefore, the claimed expandable medical device would not have been obvious to one of ordinary skill in the art.

Each of the pending independent claims 49, 59, and 74 recite a stent with first and second active agents within openings in the expandable medical device struts. At most, Santini possibly teaches the attachment of a drug chip to the inside surface of a stent. Santini clearly does not teach two active agents with openings in the stent struts. Accordingly, Santini cannot anticipate claims 49, 50, 74 and the claims depending therefrom.

In summary, Burkoth et al. teaches dual drug delivery in opposite directions, but does not teach delivery of two drugs in the same direction. Santini teaches the use of layered substrates to form microchip with two drugs. Santini does not teach or suggest the use of two drugs in a stent as claimed in the present claims.

The expandable medical device of the present invention provides a mechanism to control delivery of two or more agents from a stent while controlling both the release profile and the direction of drug delivery. This ability to control both release and directionality is not available in prior art.